REMARKS

The Office Action states claims 1-20 stand finally rejected in the previous Office Action. In fact, claims 5 and 18 were previously cancelled. Claims 1-4, 6-17, and 19-20 stand rejected. Applicant has filed a Continued Prosecution Application to further prosecute the claims.

Claims 1, 3, 6, 7, 8, 9, 10 and 11 are amended. Claims 15-17 have been cancelled and claims 21-24 have been added. For convenience, the clean version above and the attached marked-up version shows all claims currently in the case, whether or not they are amended with this preliminary amendment. To clarify further, claims 2 and 4 have been once amended since filing of the parent application. However, they are unchanged since the last reply to an office action. Claims 12-14 are unchanged since filing of the parent application. Upon entry of the amendments, claims 1-4, 6-14, and 19-24 remain pending.

Support for the amendments is found in the specification, including the claims, as originally filed. For example, support for the limitation that the gastroresistant polymer is soluble at a pH about 5.5 is found in the specification on page 4, lines 9-12. This applies to independent claims 1, 9 and 11. Support for the amendments to claims 3 and 10 are found in the specification for example at page 5, lines 4-9. Support for new claims 22-24 is found in the description of the soluble polymer noted above, and in the Examples on page 11 where a dissolution profile is given, showing 99% dissolved in 12 hours. Applicant respectfully requests entry of the amendments.

Rejection Under 35 U.S.C. § 112

Claims 1-4 stand rejected under 35 U.S.C. §, 112, second paragraph, as indefinite. The Examiner takes the position that the expression "functional coasting" renders the claims indefinite. Applicant has amended independent claim 1 to remove the term "functional coating" and replace it with the term "coating". For this reason, Applicant respectfully requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1-20 stand rejected under35 U.S.C. § 103(a) as unpatentable over Morella et al., U.S. patent 5,378,474 (the Morella reference). The Examiner states that the Morella reference teaches pharmaceutical compositions having a core element containing antihypertensive agent such as Verapamil, and further containing 35-70% wt. of a methacrylic polymer, 4-20% wt. of hydroxypropyl methylcellulose, 15-35% wt. polyethylene glycol, and 4-30% wt. of a filler such as silicon dioxide. The Office Action states that it would have been obvious to one of ordinary skill to modify the teachings of the Morella reference to arrive at the subject matter of the claims. The Office Action further states that optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. For the reasons discussed below, Applicant respectfully traverses the rejection as applied to the amended claims and requests reconsideration.

To sustain a rejection under § 103 over a single reference, the reference must teach or suggest every element of the claims, and there must be some motivation to modify what the reference discloses to arrive at the subject matter of the claims. Just because a modification can be made, the modification is not obvious unless there is a teaching that such modification would be desirable.

Applicant has amended claims 1, 9 and 11 to recite that the gastroresistant polymer present at 30-80% by weight of the coating is soluble a pH above 5.5. The Morella reference claims an analogous component at a level of 1-30%. Applicant respectfully notes that the methacrylic polymer referred to the Examiner as present at 35-75 wt. % in the Morella reference is in fact component a) of claim 1 - a matrix polymer insoluble at a pH of 1-7.5. At column, lines 36-55 and especially lines 53-55, the Morella reference explains that that a suitable insoluble matrix polymer is an acrylic acid ethyl ester (methacrylic acid) methyl ester (1:1) copolymer. This is an ester/ester copolymer. Applicant's gastroresistant polymer soluble at pH above 5.5, on the other hand, is exemplified by an acid/ester copolymer of methacrylic acid and acrylic acid ethyl ester. The Morella reference teaches a coating having 1-60%, preferably 2-20% of this component, as against the 30-80% of the amended claims.

Furthermore, the current claims require the presence of hydrophilic silicon dioxide in the coating. The Morella reference lists silicon dioxide as a possible filler in the coating (column 10, lines 4-7), but it does not disclose or suggest the use of hydrophilic silicon dioxide.

In addition, the Morella reference requires the presence of an insoluble matrix polymer in the coating. This teaching is absent from the tablet compositions of the current invention.

Finally, claims 22-24 require that the coating of the composition be soluble at a pH above 5.5. The compositions of Morella are insoluble because they contain an insoluble component, such as the ester/ester copolymer noted above.

A person of skill in the art would have no motivation to make all of the changes necessary to modify the disclosure of the Morella reference to arrive at the current claims. The modifications necessary are to provide in the tablet coating, 30-80% of the soluble polymer, whereas the Morella reference teaches 1-30%; 10-40% by weight of a hydrophilic silicon dioxide where the Morella reference teaches optional use of silicon dioxide (not hydrophilic silicon dioxide); and to completely remove the insoluble matrix polymer that the Morella reference teaches as a critical ingredient (see claim 1). Because motivation is lacking, the invention as a whole would not have been obvious to one of skill in the art. For the reasons discussed above, the amended claims are patentable under § 103 in view of the teachings of the Morella reference. Accordingly, Applicant respectfully requests that the rejections be withdrawn.

CONCLUSION

For the reasons discussed above, Applicant believes that claims 1-4, 6-14, and 19-24 are in an allowable condition and request an early notice of such allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

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ATTACHMENT FOR CLAIM AMENDMENTS

The following is a marked up version of each amended claim in which underlines indicates insertions and strike outs indicate deletions.

1. (Twice Amended) A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

b) a ~~functional~~ coating ~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of,~~ comprising, based on the weight of the coating, ~~from 0 to 30% by weight of polyethylene glycol and~~ from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5~~,~~ and ~~the non-polymer component comprises, based on the weight of the coating,~~ from 10 to 40% of a hydrophilic silicon dioxide.

2. (unchanged) A composition according to claim 1, wherein the gastroresistant polymer is selected from the group consisting of uncured poly(meth)acrylic acids, cellulose phthalates, alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

3. (Twice Amended) A composition according to claim 1, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

4. (unchanged) A composition according to claim 1, wherein the coating represents from 0.5 to 6% by weight of the core weight.

6. (Amended) ~~The~~ A composition according to claim 1, ~~in which~~ wherein the core ~~is comprised of~~ comprises granules compressed together.

7. (Amended) ~~The~~ A composition according to claim 1, ~~which~~ further ~~comprises~~ comprising an intermediate coating.

8. (Amended) ~~The~~ A composition according to claim 7, ~~in which~~ wherein the intermediate coating comprises hydroxypropylmethyl-cellulose and polyethyleneglycol.

9. (Twice Amended) A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and 10 to 80% by weight of a gelling agent; and

b) a coating ~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of~~ comprising, based on the weight of the coating, ~~from 0 to 30% by weight of polyethylene glycol and~~ from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5 comprising an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, ~~uncured poly(meth)acrylic acids, and wherein the non-polymer component comprises~~ and from 10 to 40% of a hydrophilic silicon dioxide.

10. (Twice Amended) A composition according to claim 9, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

11. (Twice Amended) A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

b) a coating ~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of~~ comprising, based on the weight of the coating, ~~from 5 to 30% by weight of polyethylene glycol and~~ from 30 to 80% of a gastroresistant polymer

soluble at a pH above 5.5 comprising an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, said copolymer imparting coating dissolution, ~~and the non-polymer component comprises~~ from 10 to 40% by weight of a hydrophilic silicon dioxide, and from 5 to 30% by weight of polyethylene glycol.

12. (Unchanged) The composition according to claim 1, providing effective release of the active ingredient for a period of at least 8 hours.

13. (Unchanged) The composition according to claim 9, providing effective release of the active ingredient for a period of at least 8 hours.

14. (Unchanged) The composition according to claim 11, providing effective release of the active ingredient for a period of at least 8 hours.

19. (Unchanged) A composition according to claim 1, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

20. (Unchanged) A composition according to claim 9, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carrogheen, polyethylene oxide, and combinations thereof.